IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bey-Dih Chang et al.		
Application No.:	10/801,207	Group:	1633
Filed:	March 16, 2004	Examiner:	Marvich, Maria
Confirmation No.:	3124		
For:	REAGENTS AND METHODS FOR IDENTIFYING AND MODULATING EXPRESSION OF GENES REGULATED BY P21		

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: _____ Signature_____

Printed Name: _____

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DECLARATION OF IGOR B. RONINSON UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Igor B. Roninson, hereby declare as follows.

1. I am a named co-inventor on the above-identified patent application. A copy of my *Curriculum vitae* is attached as Exhibit 1.
2. I have reviewed the Office Action dated January 7, 2009. I understand that claims 1 and 26 of our application are rejected as being anticipated by Fisher and Jiang. In particular, I note that the rejection states that "MDA7 is taught is induced by induction of senescence …, which is also associated with induction of p21 or mda6 … . Identification of an inhibitor of MDA7, through identification of muted MDA7 expression, results in identification of inhibitors of p21 and senescence inherently." For the reasons set forth

below, I do not agree that identification of an inhibitor of MDA7, through identification of muted MDA7 expression, results in identification of inhibitors of p21 and senescence inherently.

3. Our 2002 article (Chang,B.D., Swift,M.E., Shen,M., Fang,J., Broude,E.V., and Roninson,I.B. (2002). Molecular determinants of terminal growth arrest induced in tumor cells by a chemotherapeutic drug. Proc. Natl. Acad. Sci. U. S. A. *99*, 389-394.) addresses the question of which of the genes that are induced or repressed in senescent cells, along with p21 induction, change their expression because of p21 induction. Our study demonstrates that many of the genes that are induced in senescent HCT116 cells are induced independently of p21, although p21 is also induced in these cells. Such p21-independent senescence-associated genes would not constitute reporters claimed under our invention.
4. Fischer and Jiang demonstrate that the gene that they termed mda-7, and which is now known as IL24, is induced in melanoma cells undergoing terminal differentiation and growth arrest (they never show or suggest senescence), along with p21 (mda-6). Fischer and Jiang provide no evidence and do not even suggest that mda-7/IL24 is induced by p21. Hence, there is no reason to claim that mda-7/IL24 anticipates our reporter genes.
5. I can also add that I checked the results of our unpublished microarray analysis of the effect of IPTG-inducible p21 on the expression of all the known genes in HT1080 cells, with regard to the effects of p21 on IL24. p21 did not induce IL24 in HT1080 cells.
6. I hereby further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

So made by me this 4th date of May 2009.

/Igor B. Roninson/

Igor B. Roninson